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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------------------|------------------------|
| 10/505,313 | 03/07/2005 | Michael Bardroff | F2842 US S3 (C018016/0180) | 1924 |
| 7590 Stephen M Haracz Bryan Cave 1290 Avenue of the Americas New York, NY 10104-3300 | | | EXAMINER BALLARD, KIMBERLY A | |
| | | | ART UNIT 1649 | PAPER NUMBER |
| | | | MAIL DATE 06/05/2007 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|--|---|---|--|
| <p align="center">Office Action Summary</p> | <p>Application No.</p> <p>10/505,313</p> | <p>Applicant(s)</p> <p>BARDROFF ET AL.</p> | |
| | <p>Examiner</p> <p>Kimberly A. Ballard</p> | <p>Art Unit</p> <p>1649</p> | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 22-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-16 and 22-40 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-16, 22 and 28-30, drawn to an antibody capable of recognizing two regions of the beta-amyloid peptide, pharmaceutical compositions thereof, nucleic acid molecules, vectors, and hosts cell encoding said antibody, and method for producing said antibody.

Group II, claim(s) 23-27, drawn to a method for the optimization of an antibody molecule or preparation of a pharmaceutical composition using said optimization method.

Group III, claim(s) 31-35 and 38-40, drawn to a method of treating or preventing a disease associated with amyloidogenesis and/or amyloid-plaque formation, comprising administering an antibody capable of recognizing two regions of the beta-amyloid peptide.

Group IV, claim(s) 36-37, drawn to a method for detecting a disease associated with amyloidogenesis and/or amyloid-plaque formation.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups I-IV appears to be that they all relate to anti-A β antibodies that recognize two regions of the amyloid- β peptide, wherein the first region comprises A β 2-10 and the second region comprises A β 12-25. It is noted that the two regions defined in the claims that form the epitope recognized by the antibodies

are so close to each other that they do not necessarily form a discontinuous epitope. Therefore, any antibody cited in the prior art generated for binding to an epitope located between amino acid positions 2-25 of A β peptide could bind to the A β fragments as defined in claims 1 or 3. Accordingly, US Patent 5,688,651 to Solomon teaches the production of anti-A β antibodies generated against N-terminal fragments of amyloid- β , such as A β 8-17 and A β 1-28, which would significantly overlap with and/or encompass the instant region of A β 2-25. For example, Solomon discloses the monoclonal antibodies 6F/3D and AMY-33, which were raised against peptides 8-17 and 1-28 of amyloid- β , respectively (see column 15, lines 24-38). Such antibodies, or similar polyclonal antibodies generated against the same peptide sequences, would reasonably be expected to recognize epitopes in both of the claimed regions of amyloid- β . Therefore, the technical feature linking the inventions of Groups I-IV does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

Additionally, the PCT rules provide for the examination of the first claimed product, the first claimed method of making that product, and the first claimed method of using that product in one application, but do not provide for the examination of multiple products or multiple methods. For example, the methods use different steps and exhibit different effects, functions and/or outcomes. Accordingly, Groups I-IV are not so linked by the same or corresponding special technical feature as to form a single general inventive concept.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- A) MSR-3 antibody
- B) MSR-7 antibody
- C) MSR-8 antibody

Additionally, Applicant is required to elect a single cross-cloned antibody species, as listed in claim 10, corresponding to the elected antibody of one of A-C above.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Art Unit: 1649

MSR-3 – claims 4-7

MSR-7 – claims 4-7

MSR-8 – claims 4-7

The following claim(s) are generic: 1.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The antibodies each comprise unique amino acid and encoding nucleic acid sequences (as in claims 1-6) that do not share the same structural characteristics, and therefore the species do not relate to a single general inventive concept under PCT Rule 13.1. Similarly, the cross-cloned antibody species listed in claim 10 would each comprise unique amino acid sequences depending on the combination of heavy and light chains used, and would therefore also not share the same structural characteristics or relate to a single general inventive concept under PCT Rule 13.1.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Art Unit: 1649

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

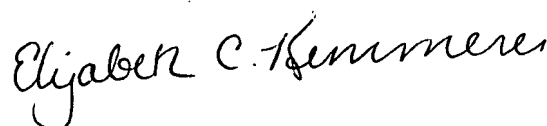
Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly A. Ballard whose telephone number is 571-272-4479. The examiner can normally be reached on Monday-Friday 9AM - 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kimberly Ballard, Ph.D.
May 24, 2007



ELIZABETH C. KEMMERER, PH.D.
PRIMARY EXAMINER